

AWARD NUMBER: W81XWH-15-2-0037

TITLE: Harnessing Neuroplasticity to Enhance Functional Recovery in Allogeneic Hand Transplant and Heterotopic Hand Replant Recipients

PRINCIPAL INVESTIGATOR: Scott H. Frey, Ph.D., Ed.M.

RECIPIENT: Washington University
Saint Louis, MO 63130

REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 14-10-2016 Oct 2016		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 8-10-2015 - 8-10-2016 15 Sep 2015-	
4. TITLE AND SUBTITLE Harnessing Neuroplasticity to Enhance Functional Recovery in Allogeneic Hand Transplant and Heterotopic Hand Replant Recipients				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-15-2-0037 W81XW-15-2-0037	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Scott H. Frey, Ph.D., Ed.M.				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Missouri: 2002 Melvin H. Marx Building, 1416 Carrie Francke Drive, Columbia MO 65211 Washington University Saint Louis, MO 63130				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT We will develop, implement and evaluate an innovative program of post-transplant rehabilitation; one that harnesses recent discoveries in neuroscience to facilitate long-term, experience-dependent adaptations within the brain's sensory and motor systems.					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF: U			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 16	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			19b. TELEPHONE NUMBER (Include area code)

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

There have been nearly 100 hands transplanted worldwide and measured by long-term retention of the graft, the success rate is well over 90%. Recovery of hand functions, however, varies considerably across patients. A primary challenge remains how to optimize function of the transplanted hand. Adaptive reorganizational changes in the brain play a significant role in recovery from peripheral nerve trauma and repair, including hand transplantation and hand replantation. Traditional approaches to rehabilitation of these patients, however, fail to make use of advances in neuroscience with proven efficacy in facilitating these adaptations. We will develop, implement and evaluate an innovative program of post-transplant rehabilitation; one that harnesses recent discoveries in neuroscience to facilitate long-term, experience-dependent adaptations within the brain's sensory and motor systems. The current approach to rehabilitation of function in allogeneic hand transplant recipients is largely the same as standard-of-care following hand replantation (re-attachment) and peripheral nerve repairs. This involves an eclectic combination of traditional therapies, few of which are actually supported by solid clinical evidence (e.g., sensory re-training). In seeking to improve on this approach, there is potentially much to be gained by considering evidence that limb amputation not only impacts the peripheral nervous system but also the brain, and tailoring interventions accordingly.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Allogeneic hand transplantation, heterotopic hand replantation, transcranial direct current stimulation, nerve repairs, rehabilitation, constraint induced movement therapy, mirror therapy.

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

- Washington University HRPO approval for Aim 3
- DoD HRPO approval for Aim 3
- Data collection on 19 participants for Aim 3
- Christine M. Kleinert Institute local IRB approval for Aims 1 & 2
- Continuing work with the DoD HRPO (contact: Nancy Englar) on overall approval of Aims 1 & 2
- Upon Dr. Frey's departure from Washington University, instatement of Dr. Catherine Lang as PI for Aim 3
- Submission of documents to the DoD to transfer the grant from Washington University to University of Missouri

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major and Minor Tasks to be Supervised by Dr. Scott H. Frey at WUOT.

1. Collaboration with Dr. Lang and Dr. Bland on development of manuals and training documents for Aim 1 & 2 protocols (months 1 – 3)
2. Preparation and submission of human use materials to the local IRB and DoD HRPO (months 1 - 6)
3. Collaboration with Dr. Lang and Dr. Bland on training of research staff at all sites (months 3 – 6)
4. Organization, scheduling and agenda coordination for biweekly meetings between CMKI, SIU, WashU research teams (months 1 – 12).
5. Communication between research sites and statistical consultant for randomization based on pre-test data. (months 9 - 12)
6. Recruitment of unilateral amputees for Aim 3 and scheduling of actigraphy sessions (months 7 – 12)
7. Troubleshooting for all research sites (months 7 - 12)
8. Assess quality of data across sites and provide corrective feedback (months 7 - 12)
9. Obtain weekly progress reports from each site and coordinate overall project management across sites (months 7 - 12)
10. Collection of dEEG data at CMKI & SIU (months 7 - 12)
11. Analysis of behavioral (other than actigraphy) and dEEG data (months 7 - 12)
12. Management and organization of all study records (months 1 - 12)
13. Quarterly report preparation (months 3, 6, 9, 12)
14. Presentation of preliminary data at conference (months – 9 - 12)
15. Oversee and host annual collaborator meeting hosted by WUOT (9 - 12)

Major and Minor Tasks to be Supervised by Drs. Kaufman and Tuna and Christine M. Kleinert Institute.

Year 1

1. Preparation and submission of human use materials to the local IRB and DoD HRPO (months 1 - 6)
2. Biweekly meetings between CMKI, SIU, WashU and research teams (months 1 – 12).
3. Recruitment of transplant, replant recipients, and nerve repair patients (months 6 - 12)
 - a. patient scheduling (months 6 - 12); b. gathering data from medical records (months 6 -12)
4. Protocol administration (months 7 – 12)
 - a. Study 1A: n = 1; Study 1B: n = 5, Study 2A: n = 0 - 1; Study 2B: n = 5
5. Quarterly report preparation (months 3, 6, 9, 12)
6. Presentation of preliminary data at conference (months 9 – 12)
7. Attend annual collaborator meeting hosted by WUOT (months 9 – 12)

Major and Minor Tasks to be Supervised by Dr. Neumeister at Southern Illinois University School of Medicine (SIU)

Year 1

1. Preparation and submission of human use materials to the local IRB and DoD HRPO (months 1 - 6)
2. Biweekly meetings between CMKI, SIU, WashU research teams (months 1 – 12).
3. Recruitment of transplant, replant recipients, and nerve repair patients (months 6 - 12)

- a. patient scheduling (months 6 - 12); b. gathering data from medical records (months 6 -12)
- 4. Protocol administration (months 7 – 12)
 - a. Study 1A: n = 1; Study 1B: n = 5, Study 2A: n = 0 - 1; Study 2B: n = 5
- 5. Quarterly report preparation (months 3, 6, 9, 12)
- 6. Presentation of preliminary data at conference
- 7. Attend annual collaborator meeting hosted by WUOT (months 9 – 12)

Major and Minor Tasks to be Supervised by WUPT, Drs. Lang and Bland

Year 1

- 1. Development of protocol manuals and training documents for CIMT, MT and actigraphy (months 1 – 3)
- 2. Assistance in preparation and submission of human use materials to the local IRB and DoD HRPO (months 1 - 6)
- 3. Travel to CMKI and SIU to train research/clinical staff in administration of protocols for Aims 1 & 2 (months 4 – 6).
- 4. Biweekly meetings between CMKI, SIU, WashU research teams (months 1 – 12).
- 5. Analysis of actigraphy data collected at other sites (months 7 – 12)
- 6. Quarterly report preparation (months 3, 6, 9, 12)
- 7. Presentation of preliminary data at conference
- 8. Attend annual collaborator meeting hosted by WUOT (months 9 – 12)

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1. Major Activities

- Frey's laboratory moved from the University of Missouri (MU) to Washington University in July 2015.
- The grant was officially received by Washington University (WU) on September 15, 2015.
- Aim 3 accelerometry procedure for individuals not participating in Aims 1 & 2 was developed by the WU OT & PT teams
- Frey's team received local IRB approval for Aim 3 of the project (the accelerometry portion that was managed by Frey, Kelli Buchanan, and Drs. Catherine Lang & Maggie Bland from WU Physical Therapy)
- Frey's team received DoD approval for Aim 3 of the project
- Collected data on 19 participants
- WU PT pre-analyzed this data

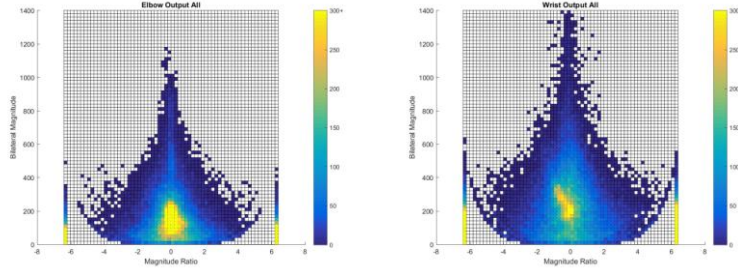
2. Specific Objectives

Many of our objectives were met in the past calendar year. We received regulatory approvals for Aim 3 of the project and began data collection and analysis. The research coordinators have maintained biweekly contact via teleconference to stay updated and informed of progress at each site. Dr. Frey and Kelli Buchanan are currently developing a project guide to ensure that administrative and protocol procedures are standardized across sites.

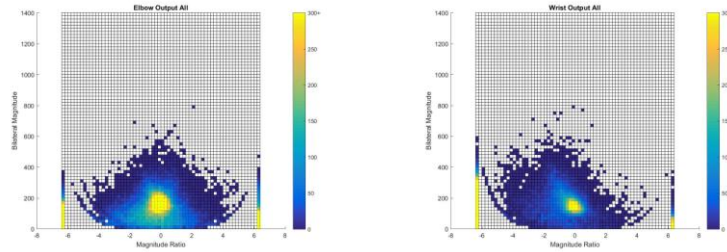
There were also several delays to the project. Southern Illinois University (SIU) has experienced continual problems with local IRB submission and still does not have local approval for Aims 1 & 2. Due to this delay, we have not started recruitment or data collection for Aims 1 & 2. Our planned solution is to involve the University of Missouri, which has a very active peripheral nerve repair program. Between orthopedic and plastic surgery, they have operated over 300 cases of distal forelimb injury in the past five years. Drs, Stephen Colbert, David Brogan and Jay Bridgeman have expressed their support and enthusiasm for this project and will provide the support needed to identify participants. As of September 1, 2016, Dr. Frey's team moved to the University of Missouri. The grant transfer process has been initiated, but we have been advised that the transfer will take between 6 months – 1 year. This will delay the entire project.

3. Significant Results

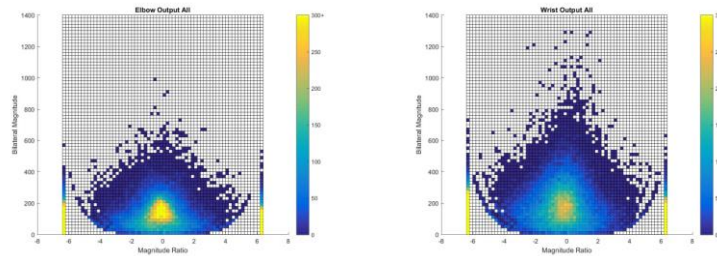
A. Healthy Young Adult



B. Right Hand Below Elbow Amputee



C. Right Hand Replant



Effects of hand loss and replantation on limb use during everyday life. Data in the left hand column was acquired from elbow-level accelerometers and data in the right hand column was acquired at the wrist or distal end of the residual limb. Data was acquired over a three 24-hour periods of everyday life. Magnitude Ratio represents the contribution of the left and right limbs. Bilateral Magnitude represents the intensity of the movement. Color indicates movement frequency. A. Healthy adults exhibit a high degree of symmetry with movements involving both limbs simultaneously being most frequent and of highest intensity. B. Right hand loss leads to a pronounced decrease in movement of the affected side at the distal wrist on the affected side, but not at the level of the elbow. However, most frequent movements still involve use of both limbs. Overall, movements tend to be of lower intensity. C. Hand replantation is associated with increased use of the affected right side especially at the distal level compared with the amputee (B), and we see increased frequency of bilateral movements.

4. Other Achievements

Dr. Frey traveled to SIU to meet with the research team and discuss the protocol. We have submitted all quarterly reports and maintain monthly contact with the DoD grants management team. Biweekly coordinator meetings have occurred to discuss administrative, regulatory and protocol issues, in addition to regular email contact.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

This project has provided professional development opportunities for Kelli Buchanan, the research coordinator working under Dr. Frey. Through one-on-one interaction and mentorship with Dr. Frey and other members of the research team, in addition to independent activity, Ms. Buchanan has taken advantage of the opportunity to learn about many facets of managing a research project, including: federal regulations regarding research, how to edit and contribute to scientific protocols and statements of work, how to manage effective and regular communications between research sites and how to troubleshoot issues. The research coordinators at CMKI and SIU had similar professional development opportunities due to their work on this project. As the project commences, it will provide research training opportunities for involved clinical staff including surgeons and therapists.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Frey's team will complete any action items necessary to ensure and/or expedite a smooth transition of grant funds from WU to MU
- Obtain regulatory approvals from local IRBs and DoD HRPO for Aims 1, 2 and 3
- Begin recruitment for all aims.
- Frey's team will continue to work internally and with the other research sites to produce and refine a standard operating procedure for Aims 1 & 2
- Drs. Bland & Frey, with assistance from Ms. Buchanan, will develop a Redcap database and/or administrative pipeline to facilitate smooth operations for Aim 3 actigraphy pre/post testing (This will necessarily involve careful coordination and timing between sites so all Aims 1 & 2 participants receive pre/post testing at the appropriate time)
- CMKI will hire hand therapists to administer protocol for Aims 1 & 2
- Frey plans to travel to CMKI to train hand therapists in tDCS administration/review general study procedures.
- Frey and colleagues will assist with troubleshooting for all research sites, when needed
- Continue biweekly coordinator teleconferences
- Continue monthly grant management teleconference
- Regular quarterly/annual report preparation
- Submit amendments, adverse events and protocol deviations as needed

4. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

We have made two changes to the statement of work that we feel will greatly facilitate progress in the project: As discussed with the grants team, and included in our quarterly reports, as a result of concerns raised by the local IRBs who had concerns about the research team traveling to test participants at other sites, we have eliminated the dense array EEG measures from Aims 1 & 2. Funds originally budgeted for this work are being used to increase the sample sizes in Aims 1 – 3.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Dr. Frey transferred to the University of Missouri, effective 8/12/16. The rest of his team moved 9/1/16. The grant is currently in the process of transition from Washington University to University of Missouri. This transfer was approved by Karen Petreore of the DoD and is estimated

to take up to six months to one year. During the transfer period, we intend to maintain regular communication with the sites, refine the administrative and protocol procedures, and hire hand therapists at each site to perform the protocol. We will seek local and DoD HRPO regulatory approval as soon as possible, so permissions will be in place when we receive approval to use funds for human research upon official receipt of grant funds at the University of Missouri.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

We have made two changes to the statement of work that we feel will greatly facilitate progress in the project: As discussed with the grants team, and included in our quarterly reports, as a result of concerns raised by the local IRBs who had concerns about the research team traveling to test participants at other sites, we have eliminated the dense array EEG measures from Aims 1 & 2. Funds originally budgeted for this work are being used to increase the sample sizes in Aims 1 – 3.

The funds budgeted for SIU's involvement in Aims 1 & 2 will be rebudgeted to increase enrollment numbers. All changes will be submitted to the DoD for approval prior to implementation.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life.

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

University of Missouri

Name: Scott H. Frey

Project Role: PI

Nearest person month worked: 1 calendar month

Contribution to project: Frey oversees the entire project. He developed the protocol and coordinates all research teams to ensure timely completion of milestones. He is working to refine the protocol by creating a reference document/operations manual that will go over protocol implantation and compliance, data quality assurance, management of data and data integration and reporting.

Name: Kelli Buchanan

Project Role : Coordinator

Nearest Person month worked: 7 calendar months

Contribution to project: Ms. Buchanan has coordinated IRB/HRPO protocol preparation and reporting at both WU and MU. She is in charge of records organization and maintenance and developing an effective administrative pipeline for site communication and transferring data between sites. She assists Dr. Frey in protocol and amendment preparation, as well as with the development of the operations manual. Ms. Buchanan works to prepare quarterly and annual reports with Dr. Frey. She also leads biweekly research coordinator meetings between sites and acts as facilitator between sites. Ms. Buchanan also assists in misc tasks as assigned by Dr. Frey or other members of the

research team. She will help Dr. Bland in developing a centralized RedCap database for the project to streamline administrative communication and data sharing.

Christine M. Kleinert Institute

Name: Christina Kaufman

Project Role: PI at CMKI

Nearest person month worked: 1

Contribution to Project: Dr. Kaufman has organized a team of researchers and therapists at CMKI to implement the protocol. She has coordinated IRB/HRPO protocol preparation and submitted the approved local protocol to the DoD HRPO. Dr. Kaufman hosted Dr. Frey and helped disseminate information about the protocol to her research team.

Washington University

Name: Catherine Lang

Project Role: PI of Aim 3

Nearest person month worked: 1 calendar month

Contribution to Project: Dr. Lang is the principal investigator of Aim 3 at Washington University. She will oversee protocol administration and actigraphy data analysis. She will also oversee actigraphy pre/post testing for all Aims with assistance from Dr. Bland. She will assist in manuscript preparation.

Name: Maggie Bland

Project Role: Research Co-investigator

Nearest Person month worked: 3 calendar months

Contribution to project: Dr. Bland is in charge of day-to-day protocol administration of Aim 3. Upon regulatory approval, she will recruit participants and be the point of contact for Aim 3. She has created a RedCap database that is used to securely store Aim 3 data and research records. This database will be expanded while the team waits for grant funds to be transferred to Mizzou. The goal of the database will be to have all sites utilize as a secure calendar/resource for communication/data repository. This database conforms to local and DoD HRPO conditionality regulations and will be a valuable resource to centralizing communication for pre/post actigraphy testing.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported

previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Yes. When Dr. Frey moved to University of Missouri, Dr. Catherine Lang took over the role of principal investigator at Washington University. An amendment stating the change of PI (with required documents, including local IRB acknowledgement of the amendment and verification that there have been no events) is being prepared for submission to the DoD HRPO.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name: Christine M. Kleinert Institute

Location of Organization: 225 Abraham Flexner Way # 650, Louisville, KY 40202

Partner’s contribution to Project: Research Collaborators, will be site of Aims 1 & 2

Organization Name: Washington University School of Medicine (Department of Physical Therapy)

Location of Organization: 4444 Forest Park Ave, St. Louis, MO 63108

Partner’s contribution to Project: Research Collaborators, coordinators and oversight of Aim 3

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

- 9. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.